

the statement "A recent test made by the Truesdail Laboratories, Inc., of August 31, 1943, shows a count of seven billion eight hundred million viable acidophilus bacteria in each fluid ounce of bottle tested," contained in the accompanying leaflet, was misleading since the article contained only a small proportion of the number of viable *acidophilus* bacteria represented by such statement; and, the statement "Acidofilac A vitalized aciduric bacterial food A composite culture of selected strains of *Lactobacilli-Acidophilus* and *Bulgaricus* in skim milk. It is best to use before Oct. 11, 1949," appearing on the label of the article, was misleading since the statement represented and suggested that in the recommended dose stated on the label the article would supply prior to the date stated a therapeutically significant number of viable *Lactobacilli acidophilus* and *bulgaricus*, whereas it would not do so.

The complaint alleged further that unless restrained, the defendant would continue to introduce and deliver for introduction into interstate commerce the adulterated and misbranded article.

PRAYER OF COMPLAINT: That the defendant be perpetually enjoined from commission of the acts complained of.

DISPOSITION: August 1, 1950. The defendant having consented to the entry of a decree, the court issued an order permanently enjoining the defendant from shipping in interstate commerce any *Acidofilac* or any like drug which was adulterated and misbranded as alleged in the complaint.

3191. Adulteration of Creme-A-Tone and adulteration and misbranding of Vextrin capsules, Trestilon tablets, Elgyn capsules, Folitrin tabsules, Slix tablets, and Estra-Beta capsules. U. S. v. Oxford Products, Inc. Plea of guilty. Fine of \$1,300, plus costs. (F. D. C. No. 28112. Sample Nos. 353-K, 354-K, 358-K, 2252-K to 2254-K, incl., 3130-K, 21365-K, 21366-K, 30739-K, 30740-K, 42129-K, 43432-K, 43433-K.)

INFORMATION FILED: June 14, 1950, Northern District of Ohio, against Oxford Products, Inc., Cleveland, Ohio.

ALLEGED SHIPMENT: Between the approximate dates of March 15, 1948, and March 14, 1949, from the State of Ohio into the States of Georgia, West Virginia, Virginia, Missouri, California, Illinois, and Michigan.

NATURE OF CHARGE: *Creme-A-Tone*. Adulteration, Section 501 (b), the article purported to be and was represented as aluminum hydroxide gel, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from the official standard; and the difference in the strength of the article from the standard was not plainly stated, or stated at all, on its label. The standard provides that aluminum hydroxide gel contains the equivalent of not less than 3.6 percent of aluminum oxide, and that the volume of tenth-normal acid required to neutralize one gram of aluminum hydroxide gel shall be not less than 12.50 cc. All shipments of the article contained the equivalent of less than 3.6 percent of aluminum oxide, and in one of the shipments the volume of tenth-normal acid required to neutralize one gram of the article was less than 12.50 cc.

Vextrin capsules, Trestilon tablets, Elgyn capsules, Folitrin tabsules, Slix tablets, and Estra-Beta capsules. Adulteration, Section 501 (c), the strength of the articles differed from that which they purported and were represented to possess. Misbranding, Section 502 (a), certain statements in the labeling

of these products relating to their declared strength were false and misleading. The statements represented and suggested:

That each *Vextrin capsule* contained 20 milligrams of iron and would supply 2 times the minimum adult daily requirement for iron;

That 4 *Trestilon tablets* would furnish 2,000 percent of the daily minimum requirement of iron for adults and 50 percent of the daily minimum requirement of calcium for adults;

That each *Elgyn capsule* contained 20 milligrams of iron and would supply 2 times the minimum adult daily requirement for iron;

That two *Folitrin tabsules* would provide the minimum adult daily requirement for iron;

That 9 of the *Slia tablets* contained 460 milligrams of calcium and 360 milligrams of phosphorus, and that 9 such tablets contained 50 percent of the minimum daily requirements for calcium and phosphorus;

That each *Estra-Beta capsule* contained 30 milligrams of niacinamide and 20 milligrams of iron and would supply 2 times the minimum adult daily requirement for iron.

The *Vextrin capsules*, *Trestilon tablets*, *Elgyn capsules*, *Folitrin tabsules*, and *Slia tablets* were deficient in the above named ingredients; and one shipment of the *Estra-Beta capsules* contained less than 30 milligrams of niacinamide, and the other shipment contained less than 20 milligrams of iron and would supply less than 2 times the minimum adult daily requirement for iron.

DISPOSITION: June 14, 1950. A plea of guilty having been entered, the court imposed a fine of \$1,300, plus costs.

**3192. Adulteration and misbranding of prophylactics. U. S. v. 50 Gross * * *
(F. D. C. No. 28891. Sample No. 68860-K.)**

LIBEL FILED: March 24, 1950, Western District of Washington.

ALLEGED SHIPMENT: On or about January 11 and February 10, 1950, by the Dean Rubber Mfg. Co., from Kansas City, Mo.

PRODUCT: 50 gross of *prophylactics* at Seattle, Wash. Examination of samples showed that 2.3 percent were defective in that they contained holes.

LABEL, IN PART: "Dean's Peacocks Reservoir Ends."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "Tested On New, Modern Equipment For Your Protection * * * An Aid In Preventing Venereal Diseases" was false and misleading as applied to articles containing holes.

DISPOSITION: September 11, 1950. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3193. Misbranding of Amberin. U. S. v. Bernard A. Brownlow (The Amberin Co.). Plea of not guilty. Tried to the court. Verdict of guilty. Sentence of 10 months in a Federal work camp. (F. D. C. No. 26737. Sample Nos 41032-K, 41036-K.)

* See also Nos. 3183, 3187, 3188, 3190-3192.